

## REMARKS/ARGUMENTS

Claims 1, 19, 23, and 27 are amended. Claim 5 is canceled. Upon entry of the amendment, claims 1-4 and 6-28 are pending in the present application.

### Claim rejections under 35 U.S.C. § 102

Claims 1-3, 6-15, 17, 19-21, 23-25, and 27-28 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bolden (US Patent No. 6,090,086). Applicants respectfully disagree with the Examiner's rejection because the cited reference does not disclose, teach, or suggest all of the elements of the present invention as claimed. As discussed below, Bolden lacks, inter alia, the teaching of an eye drop device with: (1) a capillary tube having a lower end portion that is bent at an angle and positioned adjacent to and above the lid retractor (independent claim 1), (2) the terminal ends of the discharge outlet and lid retractor extending at substantially equal angles (independent claim 19), (3) a liquid conveyor and a lid retractor having terminal portions which are bent to extend in a substantially parallel relationship (independent claim 23), or (4) a discharge end with an opening parallel to the lid retractor portion (independent claim 27). Because the cited reference does not disclose, teach, or suggest every element of the present invention as claimed, the Examiner's rejection is improper.

Amended claim 1 recites, in pertinent part (emphasis added):

a transfer portion connected to said receiver to receive liquid therefrom, said transfer portion including a capillary tube to advance a drop of said liquid by gravity and capillary action to a lower discharge outlet of the capillary tube whereat the drop of liquid breaks away and drops from the capillary tube, and

a lid retractor supported adjacent to said discharge outlet of the capillary tube, said lid retractor being adapted for being pressed against the lower lid of the subject to form a cul-de-sac between the lower lid and the eye,

said lower discharge outlet of said capillary tube having a lower end portion which is bent at an angle being positioned adjacent to and above

said lid retractor in a position to deposit the drop of liquid into the cul-de-sac.

Amended claim 19 recites (emphasis added):

A hand engageable device for administering eye drops to an eye of a subject, said device comprising liquid flow means having a terminal end for transporting liquid, one drop at a time, to a discharge outlet of the liquid flow means and lid retractor means having a terminal end adapted for being pressed against a lower lid of an eye of the subject to produce a cul-de-sac of the lower lid, said liquid flow means and said lid retractor means being integrated and arranged so that the terminal ends of said discharge outlet and said lid retractor extend at substantially equal angles such that said discharge outlet is positioned to deposit a drop of liquid into the cul-de-sac when said lid retractor means is pressed against the lower lid.

Amended claim 23 recites (emphasis added):

Apparatus for depositing a drop of liquid into an eye of a subject, said apparatus comprising a manually held instrument including a lid retractor and a liquid conveyor integrated and arranged so that liquid introduced into the liquid conveyor is advanced as a drop and deposited into an eye of a subject whose lower lid is retracted by the lid retractor, and said liquid conveyor and said lid retractor have terminal portions which are bent to extend in substantially parallel relationship.

Amended claim 27 recites (emphasis added):

A method of depositing a drop of liquid into an eye of a subject comprising:

providing an instrument having a retractor portion and a discharge end adapted for being held in one hand of the subject,

pressing, with said retractor portion of said instrument, a lower lid of the subject to form a cul-de-sac of the lower lid, and

advancing a drop of liquid in the instrument to said discharge end, said discharge end having an opening parallel to said retractor portion, wherefrom the drop of liquid falls into the cul-de-sac.

As described in the present specification and shown in Figures 2 and 3, the first embodiment of the invention has a transfer portion 15 that includes a capillary tube 16 through which the liquid passes by capillary action to a lower discharge outlet 17. The capillary tube 16 further includes a one-way valve 27 to prevent reflux of the liquid back

into the receiver (para. [0034] of the published application). During administration, a drop of liquid forms at discharge outlet 17 and breaks away, dropping from the capillary tube of the dispenser into the eye (para. [0031]). The end portion 21 of the capillary tube and an end portion 22 of the lid retractor are bent at an angle to ensure accurate dispensing of the drop of liquid (para. [0032] and Figs. 2 and 3).

Dependant claims 9-14 are directed towards a second embodiment 30 of the invention which has a unique stand alone form. (See Figs. 5 and 6) Briefly, the second embodiment comprises a loading chamber 35 (analogous to receiver 13) which is connected to a deformable air-filled bulb 36. The second embodiment is further comprised of two rod members 31 whose lower ends are fixed to the capillary tube 16. The upper ends of the rods 31 are bent to form portions 33, which are attached to the loading chamber 35. The rods are provided with finger-engaging recesses (depressions 40 and 41). As shown in Figure 6, the second embodiment incorporates a capillary tube having an end portion bent at an angle and positioned adjacent to and above a lid retractor in a position to deposit the drop of liquid into the eye (See para. [0040]-[0045]).

The structural orientation and design of both embodiments of the present invention enable the user to deposit the drop of liquid into his or her eye without requiring the user to tilt his or her head back or adopt a supine position to administer the drop. (para. [0036]) Indeed, the discharge outlet 17 of the capillary tube is designed so as to be in the optimal position for administration thus eliminating the need for any adjustment of the user's body.

Amended claim 19 is directed to a further embodiment of the present invention by reciting that the terminal ends of the discharge outlet and the lid retractor extend at substantially equal angles so as to deliver the drop of liquid into the cul-de-sac.

Amended claim 23 is directed to a further embodiment of the present invention by reciting that the terminal portions of the liquid conveyor and the lid retractor are bent to extend in a substantially parallel relationship.

Amended claim 27 is directed to a method of depositing a drop of liquid into the eye in accord with the present invention. Specifically, the method of claim 27 involves

advancing a drop of liquid to a discharge end having an opening that is parallel to said retractor portion.

Bolden discloses an eye drop dispenser fabricated from a light pliable and compressible material which allows the user to squeeze liquid from the container 12 to a nozzle 14 (Col. 4, lines 19-25). The liquid medicament 5 exits the container 12 through opening 16 at the end of the nozzle (Col. 4, lines 26-31). Gravity causes drops to fall from the nozzle, into the eye (Col. 4, lines 23-25). Bolden's eye drop dispenser also includes a flexible guide arm 20 which is manufactured from a semi-rigid material which allows the user to adjust the shape of the arm (Col. 4, lines 32-40).

It is clear that the Bolden reference does not disclose, teach, or suggest a capillary tube having a lower end portion which is bent at an angle and is positioned adjacent to and above a lid retractor in a position to deposit the drop of liquid into the eye. As illustrated in Figures 1a and 1b of the reference, Bolden teaches an eye drop dispenser that appears to require the tilting back of the user's head so as to correctly position the eye for the administration of the drop. This is in direct contrast to the present invention. As discussed above, the structure of the capillary tube of the present invention eliminates this requirement on account of its having a lower end portion that is bent at an angle. Further, Bolden does not disclose an eye drop dispenser having a one-way valve to prevent the backflow or reflux of liquid into the container 12. Nothing in Bolden even remotely suggests the structure of the device of dependant claims 9-14 as seen in Figures 5 and 6.

Finally, Bolden does not disclose, teach, or suggest an eye drop dispenser having the terminal ends of the discharge outlet and the lid retractor extend at substantially equal angles, or a dispenser having the terminal portions of the liquid conveyor and the lid retractor which are bent to extend in a substantially parallel relationship. Nor does Bolden teach or suggest a method of depositing a drop of liquid that involves advancing a drop of liquid to a discharge end having an opening that is parallel to the lid retractor portion.

Because Bolden does not disclose, teach, or suggest a device with: (1) a capillary tube having a lower end portion that is bent at an angle and positioned adjacent to and above the lid retractor (claim 1), or (2) the terminal ends of the discharge outlet and lid retractor extending at substantially equal angles (claim 19), or (3) a liquid conveyor and a lid retractor having terminal portions which are bent to extend in a substantially parallel relationship (claim 23), or (4) a discharge end with an opening parallel to the lid retractor portion (claim 27); the reference fails to anticipate the present invention. Thus, the Examiner's rejection of independent claims 1, 19, 23, and 27 is improper and should be withdrawn. Further, there is no basis for rejecting claims 1, 19, 23, and 27 as obvious.

Claims 2-4, and 6-18 all depend, directly or indirectly, from claim 1 and are patentable for at least the reasons set forth in support of claim 1. As such, some of the dependant claims are independently patentable for the at least the following reasons.

Claim 4 recites, in pertinent part: "a one way valve between said receiver and said capillary tube which permits passage into said capillary tube of said drop of liquid and prevents reflux of the liquid from the capillary tube back into the receiver." As discussed above, and the Examiner admits, Bolden does not disclose a one-way valve. Thus, claim 4 is independently patentable for at least this additional reason.

Claim 9 recites, in pertinent part: "The system of claim 1, said receiver has an upper end portion formed as a flexible bulb connected to a loading chamber."

Claim 10 recites: "The system of claim 9, further comprising finger engageable portions secured to said transfer portion to enable the subject to engage the finger engageable portions with a thumb and middle finger of one hand and press the bulb with a forefinger of the same hand to expel liquid from the device."

Claim 11 recites: "The system of claim 10, wherein said loading chamber has a valve opening for depositing liquid from a container into the loading chamber."

Claim 12 recites: "The system of claim 10, wherein said finger engageable portions include two rod members on opposite sides of said capillary tube, each rod member having a recess for engagement by a finger of the subject."

Claim 13 recites: "The system of claim 12, wherein said rod members are secured to said capillary tube."

Claim 14 recites: "The system of claim 12, wherein said rod members have lower ends fixed to said capillary tube and bent upper ends facing one another which is connected to the loading chamber."

As stated above, nothing in Bolden even remotely suggests the structure recited in dependant claims 9-14. Thus, dependent claims 9-14 are independently patentable for at least this additional reason.

Claims 20-26 depend from independent claim 19 and are patentable for at least the same reasons set forth in support of claims 1 and 19.

Claims 24-26 depend from independent claim 23 and are patentable for at least the same reasons set forth in support of claims 1 and 23.

Claim 28 depends from independent claim 27 and is patentable for at least the same reasons set forth in support of claims 1 and 27.

In sum, because the Examiner's reference fails to disclose, teach, or suggest all of the elements of the present invention as claimed, the rejection should be withdrawn. Moreover, there is no basis for rejecting the claims as obvious.

### **Claim rejections under 35 U.S.C. § 103**

Claims 4, 11, 22, and 26 stand rejected under 35 U.S.C. § 103(a) as being obvious over Bolden in view of Hanley (US Patent No. 6,869,421). Claims 5 and 16 stand rejected under 35 U.S.C. § 103(a) as being obvious over Bolden in view of Hagele (US Patent No. 6,041,978).

As required by MPEP 2143 *et seq.* to establish a prima facie case of obviousness, three basic criteria must be met:

- (1) There must be some suggestion or motivation to modify or combine the teachings of the references;
- (2) There must be some expectation of success;
- (3) The references when combined must teach or suggest all the claim limitations.

As discussed above, Bolden does not disclose, teach, or suggest all of the elements of the present invention as claimed. However, the reference combinations suggested by the Examiner also fail to disclose, teach, or suggest all of the elements, structures and relationships of the present invention recited in the claims.

The Examiner admits that Bolden fails to disclose a one-way valve. Yet despite Hanley's teaching of a one-way valve in a system for delivering a drop of liquid to the eye, Hanley does not disclose the features of the present invention that are missing from the Bolden reference.

Similarly, the Examiner admits that Bolden fails to disclose a lower end portion of the capillary tube being bent at an angle. Again, Hagele may teach a bent tube, but the Hagele reference does not disclose the other features of the present invention that are missing from Bolden.

Specifically, both combinations suggested by the Examiner fail to disclose a system for administering eye drops having a one-way valve and a capillary tube having a lower end portion that is bent at an angle and is positioned adjacent to and above a lid retractor in a position to deposit the drop of liquid into the eye. Similarly, the reference combinations fail to disclose a system for administering eye drops having a one-way valve and where the terminal portions of the liquid conveyor and the lid retractor are bent to extend in a substantially parallel direction. Lastly, the reference combinations fail to disclose a method of dispensing a drop of liquid where the drop of liquid is advanced to a discharge end having an opening parallel to the lid retractor.


Because neither combination teaches all of the features recited in the claims, the combinations fail to achieve the present invention and thus do not render the present invention obvious. As such, the rejection should be withdrawn.

Appl. No.: 10/713,890  
Amdt. dated February 15, 2006  
Reply to Office Action of December 8, 2005

For all the foregoing reasons, allowance of all pending claims is respectfully requested.

Respectfully submitted,

STEVEN T. BERGER et al

By   
Guy D. Yale  
Registration No. 29,125  
Alix, Yale & Ristas, LLP  
Attorney for Applicant

Date: February 15, 2006  
750 Main Street  
Hartford, CT 06103-2721  
(860) 527-9211  
Our Ref: BERGIB/101/US  
GDY/RAN/io

\\Alix-pw3hy3s5je\AYR\AYR saved docs\Filing Docs\BERGIB\BERGIB.101.US\BERGIB.101.US OA RESPONSE rev.doc